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No. 01-1333

Supreme Court, U.S.
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In The

Supreme Court of the United States

CAROL JEAN BROOKS,

Petitioner,

v.

HOWMEDICA, INC., a Delaware corporation and a division of Pfizer Hospital Products Group; PFIZER, INC.; and HOWMEDICA INTERNATIONAL, LTD.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eighth Circuit

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

Respondents do not contest the importance of the question presented, or the existence of directly conflicting authority among lower federal and state courts. Instead, respondents believe that the split is insufficiently dramatic, and they assert that this case is the wrong vehicle. To a certain extent their response is unresponsive to the petition, see, *e.g.*, Pet. 17-19, 21-22, 27-29 (discussing the Solicitor General's position, *Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (CA10 1997), *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (CA11 1999), and so on), and those arguments will not be repeated. Of lesser importance are respondents' arguments on the merits, which are also substantially met in the petition. A few brief points of rebuttal are, however, appropriate.

1. Specific state requirements. Respondents erroneously suggest that petitioner's suit would result in a specific state requirement because one of her experts proposed specific labeling changes. See Br. in Opp. 12, 24, 28. Even if §360k(a) somehow calls for pre-trial predictions about the character of a hypothetical judgment in petitioner's favor, the preemption argument is not advanced. Minnesota common law does not demand that the finder of fact identify an alternative warning. See Appendix to Respondents' Brief at 6, *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (CA8 2001) (No. 00-1188) (reproducing Minnesota's model jury instruction). Petitioner accordingly intends to present alternatives at trial as examples, not for a jury or judge's endorsement. Insofar as such trial presentations nevertheless raise preemption concerns, summary judgment would not be the remedy. Another expert has concluded that respondents' warnings were inadequate

as a matter of state common law, without detailing his preferred labeling. See Appendix to Petitioner's Brief at 461, *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (CA8 2001) (No. 00-1188). Regardless, petitioner contends that preemption is foreclosed on a variety of other grounds.

2. Conflict with specific federal requirements. Respondents and petitioner disagree about the standard by which eligible state and federal requirements must be compared. See, *e.g.*, Br. in Opp. 6, 8-10, 14, 19, 22-24, 27. But there should be no dispute about the regulatory record in this case, or the FDA's general policy on warning enhancements. There is no evidence that the FDA considered or opposed enhanced warnings, more detailed warnings, or alternative methods of warning product users about the disease that petitioner contracted: occupational asthma. Accord Pet. 3 (noting petitioner's unrebutted allegation that medical causation was established in 1985). It is true that in the mid-1970s, FDA reviewed (unspecified) evidence within the more general category of inhalation toxicity, and has approved a package-insert warning that refers to respiratory "irritation." Pet. 7, 22. But that is insufficient for preemption. FDA's entry into the general field of respiratory hazards could at most "trigger" preemption "analysis" – it could not end it. *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 507 (1996) (Breyer, J., concurring in part and concurring in judgment); see Pet. 23-26; see also *Goodlin*, 167 F.3d, at 1375 n.14 ("These requests for information [by FDA] may shed light upon the issues the FDA examined but do not impose any specific requirement upon the device.").

In fact, respondents' summary judgment motion was not supported by evidence that FDA has ever

rejected a proposed warning enhancement for the product at issue. See Pet. 8. The record in this case is therefore consistent with the agency's formal policy regarding warning enhancements: they are explicitly permitted, they may be implemented before agency approval, and only after FDA's response might a manufacturer find its warning proposal amended or rejected. See 21 CFR §814.39(d)(2). Considering this and other ways by which FDA can make its views known, there is no sound reason to prematurely preempt by speculating about FDA's position on specifically informing operating-room professionals about disease-specific risks. Cf. 45 Fed. Reg. 67,326, 67,327 cmt. 3, 67,329 cmt. 10 (1980) (pre-*Lohr* FDA preemption ruling concluding that a device-specific state regulation "would interfere with" the agency's own set of device-specific requirements); 42 Fed. Reg. 30,383, 30,384 cmts. 3 & 5 (1977) (noting possibility of preemption for "conflicting" state requirements).*

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* In arguing that the regulatory record in this case is exceptional, respondents are compelled to suggest a distinction between product specifications that "originate" with FDA and those that do not. Br. in Opp. 3; see *id.*, at 27. That proposed line has no basis in law, and it does not undermine the certworthiness of the petition. As the Eleventh Circuit has recognized, such distinctions would *expand* preemption protection as the quality of a manufacturer's application *declines*. Federal law does not create such counterproductive incentives: "an applicant who corrects or modifies a deficient PMA application before receiving the FDA's approval stands in no better position than an applicant whose initial PMA application was flawless." *Goodlin*, 167 F.3d, at 1375. Insofar as the Eighth Circuit held otherwise, it erred and it remains in conflict with the Eleventh Circuit.

Respondents' lack of hesitancy regarding preemption is both a weakness and a central theme of their argument on the merits. They ask the federal judiciary to supply what neither Congress nor the relevant agency has provided: a plain statement of preemption.

3. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). The argument for delay through percolation is unpersuasive. See Br. in Opp. 15, 20, 24-26; Pet. 13-16, 26-29. Although respondents speculate that anti-preemption rulings will be revised, they fail to provide any actual evidence to suggest that such reconsideration is imminent or likely. See *Webster* v. *Pacesetter, Inc.*, 171 F. Supp. 2d 1, 8-9 (D.D.C. 2001) (following *Goodlin*). In this regard, *Buckman* is useless to lower courts faced with express-preemption defenses. That opinion is overtly limited to boundaries falling far short of this case, see Pet. 28-29, and respondents have not identified any lower federal or state court yet to be confused into mistaking *Buckman* for broader meaning. The regulatory balance at issue there involved FDA's exclusive statutory authority to police fraud against itself, which implicates neither federalism concerns nor preexisting and traditional state duties of manufacturers to their product users. See 531 U.S., at 352. Finally, lower courts do not need *Buckman* to see that the PMA process is "rigorous" – a fact that by itself says nothing about whether FDA has imposed "specific" federal "requirements." *Lohr*, 518 U.S., at 497-501; *id.*, at 506-07 (Breyer, J., concurring in part and concurring in judgment); 21 CFR §808.1(d). A "rigorous" review process is neither necessary nor sufficient to create federal requirements with preemptive force against state tort claims under §360k(a).

For the reasons stated above and in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted,

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